

DD7 McCann Exh 5

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In re: National Prescription Opiate Litigation MDL no. 2804

Case No. 17-md-2804

Pharmacist Expert Opinion

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As evidence of the fact that they were late at promulgating and implementing a system of red flags, Walgreens and Walmart entered into Memoranda of Understanding or Agreement with the DEA and DOJ arising from DEA enforcement actions based upon their failure to identify and resolve these red flags of diversion in 2009-2011. CVS developed its first guidelines to pharmacists regarding warning signs of diversion only after receiving a direct warning from the DEA around the same time, later resulting in the *Holiday* decision and suspension of CVS's license.

Evidence that the abuse of opioids was well known and should have been known by the Defendants extends beyond the reports issued by the CDC, the DEA, and other credible government sources. In the face of the overwhelming evidence concerning the abuse of prescription opioid medications, the defendants failed to address the presence of the opioid prescription epidemic in their pharmacies and the significance of red flag analysis as a critical component to prevent opioid drug diversion.

In *Jones Total Health Care Pharmacy, L.L.C., and SND Health Care, L.L.C.*; Decision and Order,⁴¹ the DEA noted that an administrative law judge had “specifically rejected” the argument that a pharmacy owner, whose charged conduct occurred in the 2010-2012 time-frame, “was simply naïve or unaware of various indicia (otherwise known as red flags) that the prescriptions her pharmacy filled lacked a legitimate medical purpose as well as its contention that during the relevant time period,” and credited testimony that, in “2010, Florida pharmacists were generally aware of various red flags of abuse and diversion.” The decision also notes that, although an expert had “testified that the first reference to the term ‘red flag’ that she could find in DEA's public pronouncements was in the *Holiday* CVS decision,” that was incorrect, as “the term appears in DEA administrative decisions involving practitioners including pharmacies” earlier than that, as well as “federal court decisions that predate 2010.” *Id.* at Note 23 (citing *Paul J. Caragine*, 63 FR 51592, 51600 (1998); *Medicine Shoppe-Jonesborough*, 73 FR 364 (2008); *United Prescription Services, Inc.*, 72 FR 50397 (2007); *Medicine Shoppe- Jonesborough v. DEA*, 300 Fed. Appx. 409, 413 (6th Cir. 2008); *United States v. Alerre*, 430 F.3d 681, 686 (4th Cir. 2005); *United States v. Chin*, 795 F.2d 496, 502 (5th Cir. 1986).

The same agency decision notes that “[i]n any event, the term ‘red flag’ has been part of the lexicon for more than 200 years, and whether the Agency has used this term, or such terms as ‘warning signs’ or ‘suspicious circumstances,’ is of no consequence.” *Id.* (explaining that “[w]hat matters is whether Respondent's pharmacists either knew or were willfully blind to the fact that the controlled substance prescriptions they dispensed lacked a legitimate medical purpose”). As a matter of pharmacy practice, it is my opinion that a pharmacy chain could and should have used the data available to them, including but not limited to their own dispensing data, to assist their pharmacist and pharmacies in detecting and addressing red flags for diversion. *See* Section D. above.

⁴¹*Jones Total Health Care Pharmacy, LLC v. Drug Enf't Admin.*, 881 F.3d 823 (11th Cir. 2018), available at https://www.deadiversion.usdoj.gov/fed_regs/actions/2016/fr1110_3.htm.

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What follows is a list and description of certain red flags of diversion and the number of times that each red flag appeared in Defendants dispensing data from their pharmacies in Lake and Trumbull counties.

Red Flags of diversion can generally be categorized Prescriber Red Flags, Patient Red Flags, Prescription Red Flags and Pharmacy Red flags.

Defendants in this action have produced dispensing data from the pharmacies they operated in Lake and Trumbull counties Ohio. A number of Red Flags can be identified using the dispensing data. I have relied upon SLCG and Craig McCann to review and calculate the number of prescriptions dispensed, the amount of dosage units dispensed, and the morphine milligram equivalents dispensed for each red flag by pharmacy chain that I have identified below. These summaries can be found in Dr. McCann's report as red flags 1-16 ("Red Flags").

1. Patients traveling long distances to fill opioid prescriptions –
 - a. Pharmacy Distance- Patient generally travels over 25 miles to pharmacy.
 - b. Prescriber Distance- Patient generally travels over 25 miles to prescriber.

In the usual and customary practice of pharmacy, patients ordinarily frequent pharmacies that are convenient to their lifestyles. That convenience translates into using a pharmacy that is close to their residence or place of employment. Exceptions can occur when the individual's drug coverage under their insurance plan mandates certain pharmacies, the pharmacy that they frequent is out of a medication, or the patient is being treated by practitioners at a tertiary care facility that is highly specialized to provide services such areas as cardiac surgery, cancer treatment and management, burn treatment, plastic surgery, neurosurgery and other complicated treatments or procedures. From the data reviewed, these exceptions did not appear to be factors impacting the data. Further, according to the CDC, nearly nine out of ten Americans live within five miles of a community pharmacy.⁴² An earlier study stated that "more than 90% of Americans live within 2-miles to one of these pharmacies."⁴³ A patient that travels an inordinate distance (greater than 25 miles) to a particular pharmacy to obtain controlled substances is a recognized red flag that should be known to a pharmacist.⁴⁴ The use of 25 miles as a reference point is based upon standards used by states

⁴² CDC, Get to Know Your Pharmacist, <https://www.cdc.gov/heartdisease/pharmacist.htm>.

⁴³ Dima Qato, Shannon Zenk, Jocelyn Wilder, Rachel Harrington, Darrell Gaskin, & G. Caleb Alexander, *The availability of pharmacies in the United States: 2007–2015*, PLoS One 2017;12(8), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5559230/#pone.0183172.ref002>.

⁴⁴ In the *Holiday CVS* administrative action, a patient travelling a long distance to fill prescriptions was noted as a red flag and "indicator of possible diversion"). In *Pharmacy Doctors Enterprises, Inc., v. Drug Enf't Admin.*, 789 Fed. Appx. 724, 730 (11th Cir. 2019), customers traveling "hundreds of miles

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in establishing and permitting telepharmacies. In 2003, the North Dakota Board of Pharmacy was the first state to establish permanent rules allowing telepharmacy. North Dakota and other states utilized 25 miles or greater as one of the determinants for defining a telepharmacy in medically underserved remote rural communities.

The incidence of prescriptions for Pharmacy Distance - An opioid was dispensed to a patient who traveled more than 25 miles to visit the pharmacy. The distance here is calculated from the center of the patient's zip code to the center of the pharmacy's zip code:

Defendant	CVS	Walgreens	Walmart	HBC	Rite Aid
Date Range	1/1/2006 - 11/29/2019	1/3/2006 - 1/3/2020	1/2/2006 - 4/25/2018	1/1/2006 - 12/3/2019	1/1/2006 - 11/19/2019
Red Flag Script Count	18,433	18,226	6,315	8,893	24,300

The incidence of prescriptions for Prescriber Distance - An opioid was dispensed to a patient who traveled more than 25 miles to visit their prescriber. The distance here is calculated from the center of the patient's zip code to the center of prescriber's zip code:

Defendant	CVS	Walgreens	Walmart	HBC	Rite Aid
Date Range	1/1/2006 - 11/29/2019	1/3/2006 - 1/3/2020	1/2/2006 - 4/25/2018	1/1/2006 - 12/3/2019	1/1/2006 - 11/19/2019
Red Flag Script Count	94,941	71,686	28,530	65,224	95,186

roundtrip” was again noted as a red flag. Finally, in *East Main Street Pharmacy*, patients “driving long distances to have their prescriptions filled” was demarcated as a red flag and particularly, the “pattern of patients traveling long distances from the location of their home and physician is extremely unusual and very suspicious.” *East Main Street Pharmacy*, Affirmance of Suspension Order, 75 FR 66149-01 (October 27, 2010) (“*East Main Street Pharmacy*”).

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Additionally, NACDS included as a red flag instances where “[p]atient travels long distance to physician and/or pharmacy.”⁵²

2. Doctor Shopping

Doctor shopping, as a red flag, includes when a patient presents a prescription for a controlled substance and may be obtaining the same or similar controlled substance from a different prescriber(s) and the patient does not make the prescriber aware of the other prescriber.⁵³ The red flag assists with the identification of individuals who are searching for a cooperative prescriber who will willingly prescribe the desired controlled substances.⁵⁴

The data reveals as follows regarding patient was dispensed opioid prescriptions with overlapping days of supply that were written by two or more prescribers:

Defendant	CVS	Walgreens	Walmart	HBC	Rite Aid
Date Range	1/1/2006 - 11/29/2019	1/3/2006 - 1/3/2020	1/2/2006 - 4/25/2018	1/1/2006 - 12/3/2019	1/1/2006 - 11/19/2019
Red Flag Script Count	51,548	70,656	13,906	57,357	71,210

3. Pharmacy Shopping

Pharmacy shopping occurs as a red flag when a patient travels to multiple pharmacies to fill controlled substances prescriptions with the intent moving from pharmacy to pharmacy in the hopes of getting multiple controlled substances without being detected. In the usual and customary practice of pharmacy, the overwhelming percentage of patients (>60%) use one pharmacy as their primary source of medications. Clinically, the overall health status appeared to be the worst for patients filling at multiple pharmacies concurrently and similarly, non-adherence higher.⁵⁵

Patient was dispensed opioid prescriptions with overlapping days of supply at two or more pharmacies:

Defendant	CVS	Walgreens	Walmart	HBC	Rite Aid
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⁵²WMT_MDL_000891159.

⁵³ Stakeholders’ Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances, WAGMDL00502238; WMT_MDL_000891159.

⁵⁴ *Id.*

⁵⁵ Zachary Marcum, Julia Driessen, Carolyn Thorpe, Walid Gellad, & Julie Donohue, *Impact of Multiple Pharmacy Use on Medication Adherence and Drug-drug Interactions in Older Adults with Medicare Part D*, J Am Geriatr Soc. 2014 Feb; 62(2): 244–252.

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Date Range	1/1/2006 - 11/29/2019	1/3/2006 - 1/3/2020	1/2/2006 - 4/25/2018	1/1/2006 - 12/3/2019	1/1/2006 - 11/19/2019
Red Flag Script Count	16,040	27,008	0	8,982	22,304

Defendants' policies and documents recognized, again long after the epidemic was in full swing, that doctor shopping and pharmacy shopping were red flags:

Walmart: Patient red flags include: "evidence of "doctor shopping" and "pharmacy shopping" (often tied with traveling long distances)⁵⁶

CVS: "Doctor Shopping—Evidence of multiple doctors prescribing controlled prescriptions for customer..."⁵⁷ "Doctor shopping refers to the practice of an individual patient (who may or may not have legitimate medical issues) visiting multiple doctors in order to obtain multiple prescriptions for a controlled substance. The individual will typically have the multiple prescriptions filled at different pharmacies."⁵⁸

Walgreens: "evidence" of "doctor shopping" and "pharmacy shopping" are red flags of diversion.⁵⁹

Rite Aid: "multiple prescribers" and "multiple pharmacy locations" as a flag for all prescriptions."

Giant Eagle: "[f]urther than expected distances of the patient and/or medical provider from the pharmacy"⁶⁰ and "doctor shopping" is a "drug diversion activity"⁶¹ and "comparing the geographic location (zip code) of the patient to the location of the provider who wrote the prescription ... [and] the location of the dispensing pharmacy... [can] identify possible 'doctor shopping schemes' or 'script mills'...."⁶²

NABP Stakeholder Document

The NABP Stakeholder Report: "Patient presents a prescription for controlled substance that the pharmacist knows, or reasonably believes, that another pharmacy refused to fill."⁶³

⁵⁶ POM 1311, Practice Compliance, Proper Prescriber-Patient Relationship/Corresponding Responsibility, WMT_MDL_000042957.

⁵⁷ CVS-MDLT3-000006234.

⁵⁸ CVS-NYAG-000030739.

⁵⁹ WAGMDL00021306.

⁶⁰ HBC_MDL00191292.

⁶¹ HBC_MDL00052112, Surescripts Presentation to Giant Eagle.

⁶² HBC_MDL00043243.

⁶³ Stakeholders' Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances, WAGMDL00502238.

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4. Drug cocktails: “Holy Trinity” - An opioid, a benzodiazepine and a muscle relaxer were dispensed to a patient concurrently.

Combining drugs to achieve a desired clinical outcome, a cocktail, is an accepted means of therapy employed to treat patients diagnosed with complex conditions such as cancer or infection with the HIV virus. In these examples, the medical literature documents the effectiveness of the combinations and rationale for their use. Cocktails composed of drugs of abuse, such as opioids, lack any documented medical efficacy and conversely, are well-documented in the literature because of the dangers posed to patients, propensity for addiction, and the mimicking effects of illegal drugs such as heroin.

The Defendants’ data included prescriptions issued and dispensed for drug cocktails, particularly cocktails referred to as “Trinities.” Trinity is a broad term and can include different combinations of opioid/non-opioid prescriptions intended for abuse and to create a euphoric feeling similar to heroin and other illicit drugs.⁶⁴ The classic trinity or “Holy Trinity” consists of an opioid, a benzodiazepine, and a muscle-relaxer such as carisoprodol.⁶⁵

When combined, the three drugs produce enhanced euphoric effects beyond the effect of the individual drugs. Alarming, the combination of opioids and benzodiazepine in this trinity combination also intensifies the risk of overdose and death. All of the trinity drug cocktail prescriptions dispensed by the Defendants presented significant red flags that a pharmacist in the usual and customary practice of pharmacy would have recognized. The red flags indicated that the prescriptions were not issued for a legitimate medical purpose or in the usual course of pharmacy practice. Supporting this determination is the finding that the Defendants filled a substantial number of drug cocktails (as described above) when the three drugs were filled either

⁶⁴ Complaint, *U.S. v. Walmart Inc.*, No. 11:20-cv-01744-CFC, p. 102 (D. Del. Dec. 22, 2020).

⁶⁵ The Holy Trinity drug cocktail has been described in DEA administrative decisions as early as 2008. *See Your Druggist Pharmacy*, 73 Fed. Reg. 75,774, 75,775 n.1 (DEA Dec. 2008) - “[w]hile carisoprodol [was] not controlled under Federal law, it is controlled under various state laws and is highly popular with drug abusers, especially when taken as part of a drug cocktail that includes an opiate and a benzodiazepine.” In *U.S. v. Evans*, 892 F.3d 692, 706 (5th Cir. 2018), which arose out of charges based on conduct occurring between 2010 and 2012, it was noted that the combination of opioids, benzodiazepines, and a muscle relaxer such as carisoprodol is “a well-known and highly abused drug cocktail.” This finding was also made in other actions including, but not limited to, *East Main Street Pharmacy* - “the combination of a benzodiazepine, a narcotic and carisoprodol is well known in the pharmacy profession as being used ‘by patients abusing prescription drugs.’”; *Holiday CVS*, - citing drug cocktails issued by physician for oxycodone, benzodiazepines and carisoprodol and their abuse potential.

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at the same time or with significant overlap to alert the pharmacist that the drugs would be taken together. Further, there were additional red flags present, including but not limited to, excessive quantities and the duration of therapy outside of recommended dosages and dosing to further concern and alert the pharmacist.

Patient was dispensed an opioid, a benzodiazepine and a muscle relaxer for overlapping days of supply:

Defendant	CVS	Walgreens	Walmart	HBC	Rite Aid
Date Range	1/1/2006 - 11/29/2019	1/3/2006 - 1/3/2020	1/2/2006 - 4/25/2018	1/1/2006 - 12/3/2019	1/1/2006 - 11/19/2019
Red Flag Script Count	49,830	68,127	15,210	48,169	72,991

These concerns are heightened when the cocktail prescriptions were written by the same prescriber and filled by the pharmacy on the same day. Patient was dispensed an opioid, a benzodiazepine and a muscle relaxer on the same day and all the prescriptions were written by the same prescriber:

Defendant	CVS	Walgreens	Walmart	HBC	Rite Aid
Date Range	1/1/2006 - 11/29/2019	1/3/2006 - 1/3/2020	1/2/2006 - 4/25/2018	1/1/2006 - 12/3/2019	1/1/2006 - 11/19/2019
Red Flag Script Count	6,580	9,394	2,515	6,305	10,304

5. Drug Cocktail: An opioid and benzodiazepine.

The medical literature has shown increased risk of respiratory depression when taking an opioid with a benzodiazepine since 2002.⁶⁶ Pharmacy practice has recognized drug combinations which include opioids and benzodiazepines as being generally known as being popular with drug abusers by at least 2005.⁶⁷ In 2015, 23 percent of people who died of an opioid overdose also tested positive

⁶⁶ John Caplehorn & Olaf Drummer, *Fatal methadone toxicity: signs and circumstances, and the role of benzodiazepines*, Aust N Z Public Health, 2002 Aug; 26(4): 358-362.

⁶⁷ *East Main Street Pharmacy*, 75 FR 66149, 66163 (October 27, 2010) (drug cocktails which include benzodiazepine, opioids, and muscle relaxers are widely known in pharmacy practice as being popular with drug abusers).

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for benzodiazepines.⁶⁸ A study of over 300,000 continuously insured patients receiving opioid prescriptions between 2001 and 2013, found that people concurrently using both drugs were at higher risk of visiting the emergency department or being admitted to a hospital for a drug-related emergency. More than 30 percent of overdoses involving opioids also involve benzodiazepines.⁶⁹ Other studies highlighted the dangers of co-prescribing opioids and benzodiazepines. A cohort study in North Carolina found that the overdose death rate among patients receiving both types of medications was 10 times higher than among those only receiving opioids.⁷⁰

In the usual and customary practice of pharmacy, the combination of an opioid and benzodiazepine, both CNS depressants, would have alerted a pharmacist that the combination is dangerous and contraindicated because of the extenuated adverse effects of the drugs particularly sedation and suppression of breathing.⁷¹ The suppression of breathing is the primary the cause of overdose fatality.^{72,73} The significance of the data reviewed is the actual dispensing of this combination of drugs of abuse and the number of times the combination was dispensed despite the findings and recommendations of medical experts and guidance from the DEA and other enforcement agencies.⁷⁴

⁶⁸ Centers for Disease Control and Prevention (CDC), *Multiple Cause of Death, 1999-2015*, CDC WONDER Online (Apr. 4, 2017).

⁶⁹ Eric Sun, Anjali Dixit, Keith Humphreys, Beth Darnall, Laurence Baker & Sean Mackey, *Association between concurrent use of prescription opioids and benzodiazepines and overdose: retrospective analysis*, BMJ 2017;356: j760 (Jan. 30, 2017).

⁷⁰ Tae Woo Park, Richard Saitz, Dara Ganoczy, Mark Ilgen & Amy Bohnert, *Benzodiazepine prescribing patterns and deaths from drug overdose among US veterans receiving opioid analgesics: case-cohort study*, BMJ. 2015;350:h2698 (Apr. 15, 2015).

⁷¹ John Caplehorn & Olaf Drummer, *Fatal methadone toxicity: signs and circumstances, and the role of benzodiazepines*, Aust N Z Public Health, 2002 Aug; 26(4): 358-362; Susanne Nielsen, Paul Dietze, Nicole Lee, Adrian Dunlop, & David Taylor, *Concurrent buprenorphine and benzodiazepines use and self-reported opioids toxicity in opioid substitution treatment*, Addiction 2007 Apr;102(4):616-22; Jermaine Jones, Shanthi Mogali, Sandra Comer, *Polydrug abuse: a review of opioid and benzodiazepine combination use*, Drug Alcohol Depend. 2012; 125(1-2):8-18.

⁷² Debra Dowell, Tamara Haegerich, Roger Chou, CDC *Guideline for Prescribing Opioids for Chronic Pain — United States, 2016*, Morbidity and Mortality Weekly Reports (Mar. 18, 2016).

⁷³ Food and Drug Administration, Safety Announcement, “FDA Warns about Serious Risks and Death When Combining Opioid Pain or Cough Medicines with Benzodiazepines; Requires Its Strongest Warning” (August 31, 2016).

⁷⁴ In *Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy*, the show cause order issued on February 23, 2015 listed red flags of diversion that Zion Clinic allegedly did not resolve prior to filling prescriptions. One of the red flags noted was the dispensing of an “opiate (hydromorphone) and benzodiazepine (alprazolam, clonazepam, diazepam, or lorazepam).” 83 Fed. Reg. 10,876 at 10,877. The decision noted further that this drug cocktail was popular with drug abusers. *Id.* Similarly, in *Jones Total*

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In a 2018 discussion on opioids, Dr. Patrice Harris, the former President of the American Medical Association, made clear that organizations position on patients who present with a prescription for both an opioid and a benzodiazepine stating, “that is a deadly, potentially, deadly combination.” She went on to state that, at least in Georgia, “a lot of our overdose deaths were due to that combination.”⁷⁵

An opioid and a benzodiazepine were dispensed to a patient within 30 days of one another

Defendant	CVS	Walgreens	Walmart	HBC	Rite Aid
Date Range	1/1/2006 - 11/29/2019	1/3/2006 - 1/3/2020	1/2/2006 - 4/25/2018	1/1/2006 - 12/3/2019	1/1/2006 - 11/19/2019
Red Flag Script Count	202,125	270,454	59,014	237,898	296,410

As with the Holy Trinity, even when Patient was dispensed an opioid, a benzodiazepine and a muscle relaxer on the same day and all the prescriptions were written by the same prescriber.

Defendant	CVS	Walgreens	Walmart	HBC	Rite Aid
Date Range	1/1/2006 - 11/29/2019	1/3/2006 - 1/3/2020	1/2/2006 - 4/25/2018	1/1/2006 - 12/3/2019	1/1/2006 - 11/19/2019
Red Flag Script Count	55,880	86,616	18,943	62,515	98,933

6. Drug Cocktail: Two short-acting.

Immediate-release opioids (in contrast to extended-release or long-acting opioids) release the drugs more quickly into the bloodstream and generally have a shorter analgesic effect than extended-release drugs. Studies in the clinical literature report that immediate-release or short acting opioids are more likely to lead to more abuse and aberrant behavior than long-acting opioids because of the pharmacokinetic and pharmacodynamic features of the immediate release

Health Care Pharmacy, LLC v. DEA, 881 F.3d 823 (11th Cir. 2018), red flags were defined and included drug cocktails “known for their abuse potential, such as oxycodone and a benzodiazepine.” Accordingly, comparable determinations were made in *Holiday CVS* - the combination of an opioid and benzodiazepine like alprazolam “are commonly diverted to nonmedical use”; *East Main Street Pharmacy*.

⁷⁵ The Augusta Chronicle, “Dr. Patrice Harris Talks About Opioids,” Aug. 12, 2018 <https://www.youtube.com/watch?v=kbToYDmh16M>.

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products.⁷⁶ Pharmacists would recognize an obvious red flag when multiple prescriptions for immediate release opioids were presented at the same time or sufficiently close in time that the drugs would have overlapped.

The data detailed the repeated dispensing of prescriptions for multiple short acting opioids. Patient was dispensed two short acting opioid drugs on the same day:

Defendant	CVS	Walgreens	Walmart	HBC	Rite Aid
Date Range	1/1/2006 - 11/29/2019	1/3/2006 - 1/3/2020	1/2/2006 - 4/25/2018	1/1/2006 - 12/3/2019	1/1/2006 - 11/19/2019
Red Flag Script Count	10,650	18,409	4,937	12,946	26,163

Defendants' policies, the Stakeholders report, and NACDS recognize dangerous drug combinations as red flags:

Walmart: POM 1311 (2015): "Prescriptions presented represent a 'cocktail' of commonly abused drugs or are presented in a combination that can cause medical complications."⁷⁷ Walmart only specified in 2017 that "cocktail" included "an opioid, a benzodiazepine, and a muscle relaxant . . . often referred to as the 'trinity' or 'holy trinity'" and added "[p]rescriptions for drugs with opposite effects (e.g., stimulants and depressants)" and "prescription for drugs with similar effects (e.g., multiple long acting or multiple short acting opioids)" as additional red flags"

CVS: "Prescribes combinations the DEA has identified as having a high potential for abuse (e.g., oxycodone, alprazolam and carisoprodol)"⁷⁸

Walgreens: "Prescriptions presented represent a cocktail of commonly abused drugs."⁷⁹
Also:

JUNE 7, 2012 "Controlled Substance Action Plan"

This says "Enhanced Drug Utilization Review"

⁷⁶ Laxmaiah Manchikanti, Rajeev Manchukonda, Vidyasagar Pampati, & Kim S Damron, *Evaluation of abuse of prescription and illicit drugs in chronic pain patients receiving short-acting (hydrocodone) or long-acting (methadone) opioids*, Pain Physician 2005;8(3):257-261.

⁷⁷ WMT_MDL_000042957.

⁷⁸ ROPP 047561 – Federal Guidelines for Controlled Substances, CVS-DR22-000001011.

⁷⁹ April 2013 training guide WAGMDL0005451.

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“A DUR enhancement has been made to alert pharmacists to review a patient’s profile and utilize Good Faith Dispensing procedures when dispensing select controlled substances.

- A Major DUR will flag when a patient has been prescribed medications, that in combination, have a high potential for abuse.”
- The following message will appear to the pharmacist: “A strong association appears to exist between illicit use of Carisoprodol in combination with narcotic analgesics such as oxycodone and benzodiazepines such as alprazolam. . . .”⁸⁰

Rite Aid: Rite Aid did not list dangerous drug combinations—including the “trinity”—as a red flag at all. These combinations were simply one type of “high alert controlled substance medications” that were then subject to the procedures for validation and dispensing of high alert controlled substances (the same as a prescription for oxycodone alone).⁸¹ The only red flags which specifically mention dangerous drug combinations are (1) where “the prescriber routinely prescribes the same “cocktail” or combination of drugs for pain treatment to most or all of his/her patients, particularly where DEA and other authorities have identified the combination as potentially abused (e.g. oxycodone, alprazolam and carisoprodol or any combination of drugs from these three drug classes” and (2) review of patient’s profiles shows “only prescriptions for controlled substances in profile, or only fills for a combination of products commonly known as the ‘trinity’ (oxycodone, alprazolam and carisoprodol or any combination of drugs from these three drug classes).”⁸² Only in June 2017 did Rite Aid instruct pharmacists “when performing the NexGen red flag process for High-Risk Medications, be vigilant for prescriptions for ‘The Trinity.’”⁸³

Giant Eagle: Giant Eagle’s Controlled Substance Dispensing Guidelines (July 2013) lists (1) “prescriptions written together for: oxycodone/hydrocodone (opiate) + alprazolam (benzodiazepine) + carisoprodol (muscle relaxant as a potentiator)” and (2) “multiple prescriptions for the strongest formulations of hydrocodone and alprazolam.”⁸⁴

NABP Stakeholders Document: (1) “therapeutic duplication of two or more long-acting and/or two or more short-acting opiates (cocktails); and (2) patient presents prescriptions for highly

⁸⁰ WAGMDL00742642.

⁸¹ Rite_Aid_OMDL_0059009.

⁸² *Id.*

⁸³ Rite_Aid_OMDL_0044309.

⁸⁴ Giant Eagle, Pharmacy Controlled Substance Dispensing Guideline, HBC_MDL00191292.

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abused “cocktails” (combination of opiate, benzodiazepine, and muscle relaxant) of controlled substance medications (cocktails).⁸⁵

NACDS: includes “prescribing questionable ‘cocktails’ of commonly diverted drugs” and “prescribing combinations of drugs that can cause medical complications” as red flags.⁸⁶

7. Excessive Dispensing

Pharmacies and pharmacists engaged in the usual and customary practice of pharmacy, at the time in question, were aware of, or should have known, that opioids prescribed at any dosage presented a risk to the patient. The risk to the patient should be evaluated in order to consider the individual patient benefits and risks. A retroactive 2017 study by the Centers for Disease Control (CDC) analyzed opioid prescribing at the national level from 2006-2015 and defined high dose prescribing rates to include prescriptions with daily dosage equal to or greater than 90 MME. Other studies examining the use of opioids and associated patient risks published in 2010 and 2011 demonstrated that the risk of overdose progressively increased at prescribed opioid dosages exceeding 20, 50, and 100 MME per day^{87,88,89} and detected causal associations of prescribed opioids with overdose deaths.^{90,91}

Additionally, a manuscript published in the Journal of the American Medical Association (JAMA) in 2016 discussing the CDC Guideline for Prescribing Opioids for Chronic Pain—United States, reported that “opioid-related overdose risk was dose-dependent, with higher opioid dosages associated with increased overdose risk. Compared with dosages of 1 to less than 20 MME per day, dosages of 50 to less than 100 MME per day were found to increase risks for opioid overdose by factors of 1.9 to 4.6, with absolute risk difference approximation of 0.15% for fatal overdose and 1.40% for any overdose. Dosages of 100 MME or more per day were found to increase risks for opioid overdose by factors of 2.0 to 8.9 relative to dosages of 1 to less than 20 MME per day, with absolute risk difference approximation 0.25% for fatal overdose and 4.04% for any overdose.

⁸⁵ Stakeholders’ Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances, NABP_00022121.

⁸⁶ NABP_00019878.

⁸⁷ Kim Dunn, Kathleen Saunders, Carolyn Rutter, et al., *Opioid prescriptions for chronic pain and overdose: a cohort study*, Ann Intern Med 2010;152:85–92.

⁸⁸ Amy Bohnert, Marcia Valenstein, Matthew Bair, et al., *Association between opioid prescribing patterns and opioid overdose-related deaths*, JAMA 2011;305:1315–21.

⁸⁹ Tara Gomes; Muhammad M. Mamdani; Irfan A. Dhalla; et al., *Opioid dose and drug-related mortality in patients with nonmalignant pain*, Arch Intern Med 2011;171:686–91.

⁹⁰ Leonard J. Paulozzi, Christopher M. Jones, Karin A. Mack, Rose A. Rudd, *Vital signs: overdoses of prescription opioid pain relievers—United States, 1999–2008*, MMWR Morb Mortal Wkly Rep 2011;60:1487–92.

⁹¹ Susan Okie, *A flood of opioids, a rising tide of deaths*, N Engl J Med 2010;363:1981–5.

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Veteran Administration's patients with chronic pain who died of overdoses related to opioids were found to have been prescribed higher mean opioid dosages (98 MME/d) than controls (48 MME/d) and that above 200 MME per day, there was a continued increase in mortality rates.”⁹²

The presentation of a prescription for an excessive quantity of an opioid, or multiple opioids on the same day or within a period of time to cause overlap, was known or should have been known as a red flag requiring action by the pharmacist before dispensing the drug. That action would need to determine whether a legitimate patient-prescriber relationship existed validating the issuance of the prescription, the safety of the prescribed drug and dose(s) for the patient (particularly any dose exceeding recommended and safe dosages and MME values of greater than 90MME per day), and the possible existence of fraud or diversion.

Despite the obvious red flags, the Defendants repeatedly dispensed prescriptions that consisted of excessive quantities and dangerously high doses as noted below.

Patient was dispensed an opioid prescription of over 200 MME per day before 2018 or over 50 MME per day after January 1, 2018.

Defendant	CVS	Walgreens	Walmart	HBC	Rite Aid
Date Range	1/1/2006 - 11/29/2019	1/3/2006 - 1/3/2020	1/2/2006 - 4/25/2018	1/1/2006 - 12/3/2019	1/1/2006 - 11/19/2019
Red Flag Script Count	14,079	33,575	2,909	13,398	47,794

In addition, when the prescriptions are analyzed by examining where a patient was dispensed an opioid prescription of over 200 MME per day before 2018 or over 90 MME per day after January 1, 2018:

Defendant	CVS	Walgreens	Walmart	HBC	Rite Aid
Date Range	1/1/2006 - 11/29/2019	1/3/2006 - 1/3/2020	1/2/2006 - 4/25/2018	1/1/2006 - 12/3/2019	1/1/2006 - 11/19/2019
Red Flag Script Count	10,742	26,633	2,909	9,176	41,388

⁹² Deborah Dowell, Tamara M. Haegerich, & Roger Chou, CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016JAMA. 2016 April 19; 315(15): 1624–1645. doi:10.1001/jama.2016.1464.

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Defendants' policies and the NABP Stakeholders report recognize excessive dispensing as a red flag:

Walmart: "prescription is for a large quantity (especially controlled substances)"/ "prescription is for a large number of a particular strength" (POM 1311 2009)⁹³, "prescription presented is for an unusually large quantity or high starting dose" (POM 1311 2015).⁹⁴

CVS: "Appropriateness of Therapy: Overprescribing large doses of controlled substances to patients." (Note in 2012 they told pharmacists to contact prescriber if "concerns" about type and quantity "e.g., oxycodone 30 mg prescriptions for more than 180 dosage unit").⁹⁵

Walgreens: "Prescriptions presented is for an unusually large quantity or high starting dose."⁹⁶ The Good Faith Dispensing program notes: "Increased frequency of prescriptions for same controlled drug: for quantities beyond those normally prescribed."⁹⁷ It also asks whether there is a trend, "unusual dosages, directions, or quantities beyond those normally prescribed."⁹⁸

Rite Aid: "Prescription is for an excessive quantity" and "Question high doses of controlled substances with excessive quantities for patients new to Rite Aid."⁹⁹

Giant Eagle: Giant Eagle's Controlled Substance Dispensing Guidelines (July 2013) lists "Large quantity of medication on a prescription from an emergency room."¹⁰⁰ NABP Stakeholders Report: "Patient presents prescriptions for large quantities or large number of prescriptions for controlled substances."

8. Pattern Prescribing

Pattern prescribing presents as a red flag when prescriptions are presented by multiple patients for the same medications, same strengths, approximately same quantities, and directions for use.¹⁰¹

⁹³ WMT_MDL_000069077.

⁹⁴ WMT_MDL_000042957.

⁹⁵ 2012, ROPP-0061 – Protocol for Dispensing Narcotic Drugs for Pain Treatment, CVS-MDLT1-000081566.

⁹⁶ WAGMDL00054510 (Note this is not in GFD, this is in training "Pharmacist GFD Review").

⁹⁷ WAGMDL00008106.

⁹⁸ *Id.*

⁹⁹ Rite_Aid_OMDL_0044309.

¹⁰⁰ HBC_MDL00191292.

¹⁰¹ *Pharmacy Doctors Enterprises, Inc.*, 789 Fed. Appx. at 730 ("prescriptions written by the same doctor on the same day for the same strength of the same drug" is a red flag); *East Main Street Pharmacy*, *supra*, at 66157 ("[a]dditional red flags include '[m]aximum doses being seen for every single patient, lack of individuation of therapy, certain patterns from physicians of potential abuse of seeing the same types of controlled substances over, and over, and over, again.'"); *Holiday CVS*, *supra*, at 62318 ("prescriptions for

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Prescribing the same medications to multiple patients erroneously supposes that the patients suffered from the same disease, exhibited the same symptoms, possessed identical patient factors (height, weight, metabolism rate, and allergies for example), took other medications that were identical, and suffered from the same adverse effects or contraindications. Clinically and in the usual and customary practice of pharmacy, this is not the case and would have served as a red flag regarding the prescribing of the practitioner and validity of the prescriptions.

Same Day Prescribing – An opioid was dispensed to at least 4 different patients on the same day and the opioid prescriptions were for the same base drug, strength and dosage form and were written by the same prescriber:

Defendant	CVS	Walgreens	Walmart	HBC	Rite Aid
Date Range	1/1/2006 - 11/29/2019	1/3/2006 - 1/3/2020	1/2/2006 - 4/25/2018	1/1/2006 - 12/3/2019	1/1/2006 - 11/19/2019
Red Flag Script Count	16,826	38,588	1,700	8,928	32,648

Same Hour Prescribing – An opioid was dispensed to at least 3 different patients within an hour and the opioid prescriptions were for the same base drug, strength and dosage form and were written by the same prescriber:

Defendant	CVS	Walgreens	Walmart	HBC	Rite Aid
Date Range	1/1/2006 - 11/29/2019	1/3/2006 - 1/3/2020	1/2/2006 - 4/25/2018	1/1/2006 - 12/3/2019	1/1/2006 - 11/19/2019
Red Flag Script Count	9,365	11,626	2,404	19,781	9,543

Defendants’ policies recognize pattern prescribing as a red flag:

the same drugs, the same quantities from the same doctor without any kind of variability or change considering the different patients that come into the pharmacy” is a red flag); *Id.* at 62333 (identifying “pattern prescribing” by a physician as an “unresolvable” red flag).

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Walmart POM 1311 (2015): “Prescriber prescribes the same medication, with the same directions, for the same quantity for a large number of individuals.”¹⁰²

CVS: Prescribe the same medication in the same dosage amount to most or all of their patients”¹⁰³ and “Routinely prescribes the same combination of pain drugs for most or all of their patients.”¹⁰⁴

Walgreens: “Prescriber prescribes the same medication, with the same directions, for the same quantity for a large number of individuals.”

Rite Aid: “The prescriber writes for the same or similar medications in the same dosage quantities to most or all of his/her patients” (e.g., oxycodone 30mg, 180 dosage units)” and “The prescriber routinely prescribes the same “cocktail” or combination of drugs for pain treatment to most or all of his/her patients.”

Giant Eagle: “Lack of individualization of dosing.”¹⁰⁵

9. Early fills/refills –

- a. An opioid prescription was refilled more than 5 days before the patient’s previous prescription should have run out.

As trained pharmacists and licensed pharmacies were aware, when an individual requests that a controlled-substance prescription be filled significantly early, it raises a red flag regarding abuse or other diversion because it suggests that the individual is either taking a higher quantity than prescribed or diverting at least some of the medications to other individuals.

An opioid prescription was refilled more than 5 days before the patient’s previous prescription should have run out:

Defendant	CVS	Walgreens	Walmart	HBC	Rite Aid
Date Range	1/1/2006 - 11/29/2019	1/3/2006 - 1/3/2020	1/2/2006 - 4/25/2018	1/1/2006 - 12/3/2019	1/1/2006 - 11/19/2019
Red Flag Script Count	3,440	3,160	824	4,752	5,262

¹⁰² WMT_MDL_000042957.

¹⁰³ 2012, ROPP-0061 – Protocol for Dispensing Narcotic Drugs for Pain Treatment, CVS-DR22-000001062.

¹⁰⁴ *Id.*

¹⁰⁵ HBC MDL00191292.

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Defendants' policies and the Stakeholders report recognize early fills/refills as a red flag:

Walmart: Walmart had a policy, POM 1318 (2011),¹⁰⁶ that directly addressed filling controlled substances early. Walmart's pharmacy management software, Connexus, alerted pharmacists when requests were made to fill prescriptions more than 72 hours ahead of the next permitted fill date of a controlled-substance prescription. In 2015, Walmart added "individual routinely attempts to obtain an early refill on controlled substances." POM 1311 (2015).¹⁰⁷ In 2019 Walmart added "An *unjustified* early refill request" as a red flag in POM 1311 (emphasis added).¹⁰⁸

CVS: "Early fill – Customer attempting refill early or consistently showing up at the first available moment when refill can be obtained under standard practices." (2014).¹⁰⁹

Walgreens: "Consistent requests for early refills" or "Individual routinely attempts to obtain an early refill on controlled substances"¹¹⁰ (As of 2013, used 8 days early for a 30-day supply, 90-days supply should be X days/percent (WAGMDL00437788)).

Rite Aid: "Early refills on controlled substances, where they paid cash stating lost prescription, going away on vacation, etc." Rite Aid explains that "[e]arly refills for controlled substances should not occur more than 48 hours in advance (if allowed by State law) of the scheduled exhaustion of their current prescription supply based on the directions provided by the prescriber."

Giant Eagle: "Requests for early dispensing of refills."¹¹¹

Stakeholders (includes CVS, Rite Aid, and Walgreens): "Pattern" of "frequently running out of medication for controlled substances early" and "controlled substance refill patterns being inconsistent with regular refill patterns for non-controlled chronic prescription medications."

10. Opioids Days' Supply

Opioids are inherently dangerous drugs that require strict adherence to the recommended doses and duration in order to avoid patient harm and reduce the risk of addiction and abuse. Prescription opioids and heroin are chemically similar and can produce a similar euphoric feeling or high. Prescription opioids used for pain relief should be prescribed and taken for a short time given their addictive properties and binding to and activation of¹¹² opioid receptors on cells located in many areas of the brain, spinal cord, and other organs in the body, especially those involved in feelings

¹⁰⁶ WMT_IN_AG_00000153.

¹⁰⁷ WMT_MDL_000042957.

¹⁰⁸ WMT_MDL_000067636.

¹⁰⁹ See March 2011, Course #800131, Biannual Compliance Training, CVS-NYAG-000030693.

¹¹⁰ 6/2011 Controlled Substance Prescriptions and GFD, WAGMDL00054509.

¹¹¹ HBC MDL00191292.

¹¹² National Institute of Drug Abuse. Prescription Opioid Drug Facts, May 2020.

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of pain and pleasure. When opioids attach to these receptors, they block pain signals sent from the brain to the body and release large amounts of dopamine throughout the body. This release can strongly reinforce the act of taking the drug, making the user want to repeat the experience. A patient prescribed opioids for longer than six months is not generally accepted medical treatment and is a red flag of diversion.

A patient was dispensed more than 210 “days of supply” of all opioids combined in a 6-month period:

Defendant	CVS	Walgreens	Walmart	HBC	Rite Aid
Date Range	1/1/2006 - 11/29/2019	1/3/2006 - 1/3/2020	1/2/2006 - 4/25/2018	1/1/2006 - 12/3/2019	1/1/2006 - 11/19/2019
Red Flag Script Count	98,728	152,734	30,144	89,385	193,526

11. Payment for an opioid by cash^{113,114,115}

Paying cash for a prescription is a red flag of diversion. Oftentimes people who are paying cash for opioids are engaged in diversion and seek to obfuscate the purchase of controlled substances from review by payors and insurance companies. The likelihood of diversion increases in circumstances in which the patient pays for an opioid prescription with cash when they otherwise have insurance. The various programs that cover the cost of prescription medications afford little need to pay cash for prescriptions that would likely be covered by insurance thus avoiding out-of-pocket expenses for the individual.^{116, 117}

¹¹³ Federal Register / Vol. 83, No. 49 / Tuesday, March 13, 2018 / Notices.

¹¹⁴ Federal Register / Vol. 81, No. 218 / Thursday, November 10, 2016 / Notices.

¹¹⁵ Federal Register / Vol. 75, No. 207 / Wednesday, October 27, 2010 / Notices.

¹¹⁶ Federal Register / Vol. 81, No. 218 / Thursday, November 10, 2016 / Notices.

¹¹⁷ *Jones Total Health Care Pharmacy, LLC*, 881 F.3d at 828 (“cash purchases” of prescriptions is a red flag); *Pharmacy Doctors Enterprises, Inc.*, 789 Fed. Appx. at 730 (cash payments for prescriptions is a red flag); *Holiday CVS, supra*, at 62318, fn. 9 (cash payments for prescriptions is a red flag); 62326 (“large quantities of people paying cash” is a red flag), 62331 (“patients between the ages of 25 and 40 with cash” is a red flag), 62332 (“According to [Dr.] Doering [DEA expert], ‘typically, people who may be diverting or otherwise misusing their drugs will pay cash.’”); *East Main Street Pharmacy, supra*, at 66150 (high percentage of cash payments compared to national average is a red flag); *id.* 66158 (according to Dr. Sullivan, the DEA’s testifying expert, this “is an obvious example of a pharmacy profiting from drugs that are most likely being abused or diverted for sale on the street” and that “[a]ny reasonable pharmacist knows that a patient that wants to pay cash for a large quantity of controlled substances is immediately suspect”).

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A patient was dispensed an opioid and paid cash:

Defendant	CVS	Walgreens	Walmart	HBC	Rite Aid
Date Range	1/1/2006 - 11/29/2019	1/3/2006 - 1/3/2020	1/2/2006 - 4/25/2018	1/1/2006 - 12/3/2019	1/1/2006 - 11/19/2019
Red Flag Script Count	47,919	41,337	33,543	33,774	20,777

Defendants' policies and the Stakeholders report recognizes cash payments as a red flag:

Walmart POM 1311 (2015): "Individual insists on paying cash or insists on paying cash for controlled substances even though insurance is on file."¹¹⁸

CVS: "Cash – Cash payment for prescriptions, particularly if RxConnect indicates the patient has insurance." In 2011, 6.2.11 Identifying Forged or Altered Prescriptions. "Patient asks to pay cash for prescription."¹¹⁹

Walgreens: "Individual pays cash, or insists paying cash for controlled substances even though insurance is on file." "Does the patient request to pay by cash or by using a cash discount card (in a possible attempt to circumvent third party billing restrictions)"¹²⁰

Rite Aid: "Payment trends (e.g., always pays cash for controlled substances, but has insurance)." Later, Rite Aid added flags for prescriptions "paid for by Cash and/or Discount Cards."¹²¹

Giant Eagle: "Cash transactions on controls."¹²²

NABP Stakeholders Document: "Requesting to pay cash for a controlled substance prescription, when it has been documented that he/she has insurance that would normally cover the prescription (cash)."

NACDS – "Patient pays with cash," citing *Holiday and East Main*, in which nearly 87% of a physician's patients "paid case for their prescriptions," a "red flag as '[a]ny reasonable pharmacist knows that a patient that wants to pay cash for a large quantity of controlled substances is immediately suspect.' *East Main*, 75 FR at 66164."¹²³

Summary of Red Flags

¹¹⁸ WMT_MDL_000042957.

¹¹⁹ ROPP-00059, CVS-MDLT1-000081559.

¹²⁰ GFD, at 742668.

¹²¹ Rite_Aid_OMDL_0044327.

¹²² HBC_MDL00191292.

¹²³ WMT_MDL_000891159.

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The number of red flags identified in Defendants' dispensing data is indicative of a pattern of diversion in Lake and Trumbull counties. Roughly 44% of all prescriptions dispensed by the Pharmacy Defendants in Lake and Trumbull counties contained red flags indicative of diversion. Every red flag must be resolved before each prescription for a controlled substance is dispensed. The volume of red flagged prescriptions dispensed in these counties is unreasonable. Opioids are extremely addictive and highly subject to abuse as a result, all red flags are concerning. One would expect given the dangerous nature of these drugs and the presentation of well-known red flags that only a small percentage of prescriptions would be dispensed with unresolved or unresolvable red flags.

Red flags need not always be specific to the prescription being presented. A pharmacy should also be reviewing its dispensing data to take into consideration the totality of the circumstances, including the practitioner's prescribing patterns across different patients, e.g., large quantities, high-risk combinations, and similar diagnosis codes. That "totality of responsibility" requires the pharmacy or DEA registrant corporation to monitor the overall controlled substance volume and pertinent dispensing data. *See e.g., United States v. Lawson*, 682 F.2d at 483 ("Lawson willingly ignored every signal that he should question the volume of controlled drugs being dispensed from his pharmacies.").¹²⁴ When a prescription contains a red flag that is not resolved, each subsequent prescription for that patient or prescriber is subject to flagging until all prior flags have been investigated and resolved.

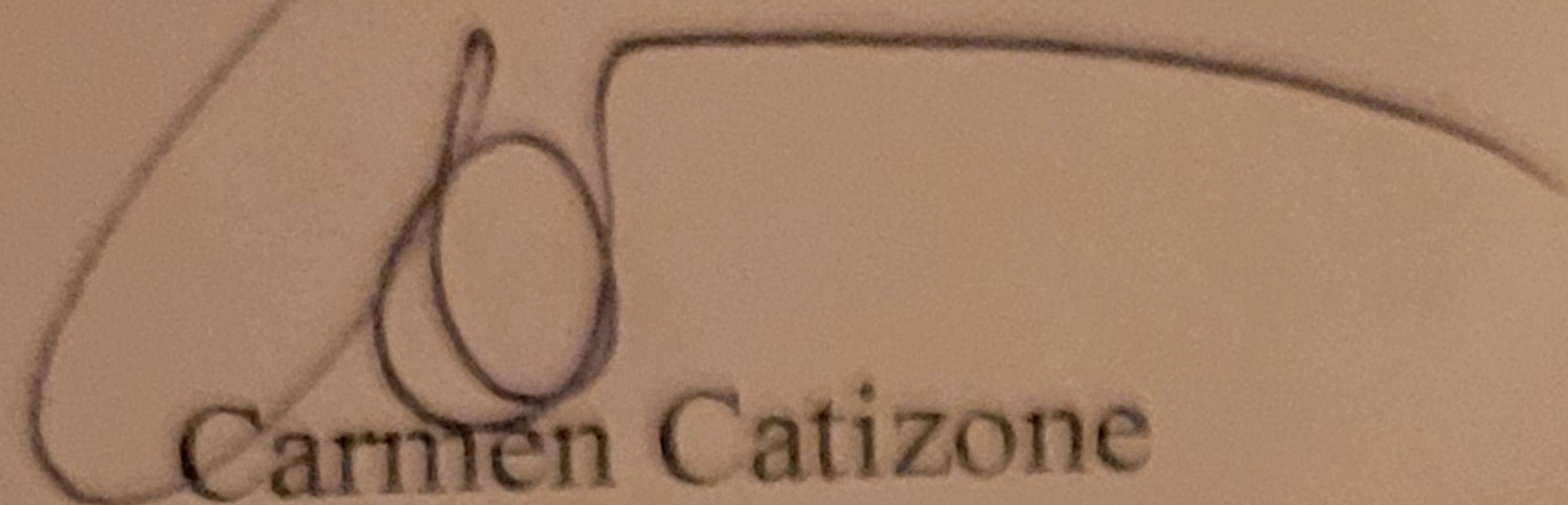
In situations where diversion is suspected, the pharmacist and the pharmacy have a responsibility to report this suspicion to the appropriate regulatory and law enforcement authorities and document the facts of the situation and actions taken and refuse to fill the prescription.

The Defendants all participated in identifying and memorializing the following additional red flags of diversion:

- Physician writes large number or percentage of prescriptions for controlled substances.
- Recurring pattern of prescribing the same controlled substances to multiple patients which suggests the physician is operating a pill mill.
- Physician engages in the unauthorized practice of medicine.
- Physician no longer holds a DEA license.
- Pharmacy and/or pharmacist has excessive volume and rate of growth of dispensing controlled substances.

¹²⁴ *See also* Deposition of former DEA diversion investigator Demetra Ashley, Ashley Dep. 132-134, stating that Chain Pharmacies could do the same red flag searches of their own computerized databases, and that it would be "reasonable" to expect pharmacies to access those databases to look for red flags, especially in the midst of a raging epidemic.

Respectfully submitted,



Carmen Catizone

Executed on April 16, 2021

Carmen Catizone